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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/412,268	10/05/99	PARHAMI-SEREN	B	MGH-1526

HM22/1002

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EXAMINER	
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ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/412,268	Applicant(s) Parhami-Seren et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 6, 1999*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-38* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

1. Claims 1-38 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-38-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1-6 and 38 are drawn to a monoclonal antibody and hybridoma cell line in Class 530, subclass 387.1 and Class 435, subclass 326.

Group II. Claim 7 is drawn to a method of making a monoclonal antibody or antigen binding fragment thereof that is specific for a hapten classified in Class 530, subclass 387.3.

Group III. Claims 8-11 are drawn to a method of making a monoclonal antibody or antigen binding fragment thereof having binding specificity for oubain, classified in Class 530, subclass 387.3.

Group IV. Claims 12-14 are drawn to a method of identifying ouabain or a ouabain-like compound with an antibody classified in Class 435, subclass 7.1.

Group V. Claims 15-17 are drawn to a method of monitoring a ouabain-like compound or digitoxin with an antibody classified in Class 435, subclass 7.1.

Group VI. Claims 18-20 are drawn to a method of diagnosing hypertension, classified in Class 435, subclass 7.1.

Group VII. Claims 21-23 are drawn to a method of diagnosing congestive heart failure, classified in Class 435, subclass 7.1.

Group VIII. Claims 24-26 are drawn to a method of diagnosing cardiomyopathy, classified in Class 435, subclass 7.1.

Group IX. Claims 27-29 are drawn to a method of diagnosing renal failure, classified in Class 435, subclass 7.1.

Group X. Claims 30-32 are drawn to a method of diagnosing salt sensitivity, classified in Class 435, subclass 7.1.

Group XI. Claims 33-35 are drawn to a method of treating cardiac glycoside toxicity, classified in Class 424, subclass 1301.

Group XII. Claims 36-37 are drawn to a method of treating hypertension, classified in Class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions II-XII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups I and IV-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as producing an anti-idiotypic antibody to the claimed antibody.

Inventions II/III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by synthetic peptide synthesis.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Groups I, III-XII are further subject to election of a single disclosed species.

Claims 1, 8, 12, 15, 18, 21, 24, 27, 30, 33, 36 are generic to a plurality of disclosed patentably distinct species comprising antibodies with different structures

and functions wherein the antibodies are (a) 1019, (b) 5A12, (c) 7-1, (d) 8E4 all recited in Claims 5, 6, 9, 14, 17, 20, 23, 26, 29,.32, 34, 37 All claims in each group will be examined as they are drawn to the elected species.

6. Groups I, III-XII are further subject to election of a single disclosed species.

Claims 1, 8, 12, 15, 18, 21, 24, 27, 30, 33, 36 are generic to a plurality of disclosed patentably distinct species comprising samples with different structure and function wherein the samples are (a) plasma, (b) serum, (c) urine. All claims in each group will be examined as they are drawn to the elected species.

7. Claims XI and XII are further subject to election of a single disclosed species.

Claims 33 and 36 are generic to a plurality of disclosed patentably distinct species comprising molecules with different structures and functions wherein the molecules are (a) ouabain, (b) digitoxin recited in claims 35 and 37.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
September 30, 2001